Establishing and using an uncertainty budget for dose to product

Miller, Arne; Helt-Hansen, Jakob

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

Establishing and using an uncertainty budget for dose to product

Arne Miller and Jakob Helt-Hansen Risø High Dose Reference Laboratory
Risø DTU - Technical University of Denmark, Roskilde, Denmark

This poster shows the main components of uncertainty to be taken into account for irradiation of product.
Radiation sterilization of medical devices is taken as an example, but the principles apply to any product irradiation process.
The uncertainty analysis is carried out considering minimum dose only. A parallel exercise can be carried out with respect to maximum dose.

The intention of this poster is to show the link between traceability and uncertainty, and to discuss how to use these in specifying the irradiation process.

Example:

Facility	10 MeV Electron accelelerator
Calibration of dosimeters	In-Plant calibration method
Process:	Medical device sterilization
Sterilization dose D_{ste}, kGy	**25**

Uncertainty budget - VIM definition:
statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination

All uncertainty components are given at 1 s.d.
Uncertainty values are given as examples only!

Facility variation

The dose delivered by the facility can vary with time.
Short-term variations during calibration mean that the doses to the transfer dosimeter and the dosimeter to be calibrated might differ.
Long-term variations during process irradiation mean that dose to product might vary.
The key parameters giving rise to potential facility variation are beam energy, current and width, plus conveyor speed. Information about these uncertainties and their variability are obtained during Operational Qualification (OQ).

	Variation of energy	Variation of beam width	Variation of beam current	Variation of conveyor speed	Facility variation
Calibrate	0.5	0.5	0.5	0.5	1.0
Process	1	2	1	2	3.2

Transfer dosimeter uncertainty

Transfer dosimeter is calibrated in reference gamma field, transferred to electrons and measured at electrons

	Calib at gamma	Transf to e-beam	Meas at e-beam	Uncertainty of transfer dosimeter
	1.7	1	0.7	
Calibrate				2.0
Measure				0.7
s(Dref)				2.1

In-plant calibration of dosimeters

Calibration by in-plant irradiation limits effects of influence factors.
Dose to the dosimeters to be calibrated is measured with transfer dosimeters.
Due to possible facility variation the doses might not be equal. The dosimeter response must be measured. The calibration function must be established.
These factors contribute to the uncertainty of the calibration.

In plant calibration of routine dosimeter

Uncertainty of transfer dosimeter calibrated at reference gamma field	Facility variation during calibration and dose map irradiation	Uncertainty of dosimeter response measurement	Uncertainty of calibration function establishment	Calibration uncertainty of routine dosimeter
2.1	1.0	1	0.7	2.6

In-plant calibration of dose map dosimeter

Uncertainty of transfer dosimeter calibrated at reference gamma field	Facility variation during calibration and dose map irradiation	Uncertainty of dosimeter response measurement	Uncertainty of calibration function establishment	Calibration uncertainty of dose map dosimeter
2.1	1.0	1.5	0.7	2.8

Measurement of routine dose during dose map

During Performance Qualification (PQ) dose mapping, the routine dose and its uncertainty are measured.
The uncertainty of response measurement can be the same as during calibration, because reference conditions are used.

Calibraiton uncertainty of routine dosimeter	Facility variation during calibration and dose map irradiation	Uncertainty of routine dosimeter response measurement	Uncertainty of measured routine dose (dose map)
2.6	1.0	1	3.0

Measurement of minimum dose during dose map

During Performance Qualification (PQ) dose mapping, the minimum dose to product and its uncertainty are measured.
The uncertainty of response measurement might be greater than during calibration due to non-reference conditions.
Possible product variation box-to-box might be significant.

Calibration uncertainty of dose map dosimeter	Facility variation during calibration and dose map irradiation	Uncertainty of dose map dosimeter response measurement	Product variation box-to-box	Uncertainty of measured minimum dose (dose map)
2.8	1.0	2	3	4.7

Irradiation of product for sterilization

During product irradiation routine dose is measured. Uncertainty of routine dosimeter respopnse measurement might be the same as during calibration because reference conditions are used. Acceptable limits for the variation of the measured routine dose are selected based on the uncertainty data obtained during calibration, OQ and PQ.

Calibraiton uncertainty of routine dosimeter	Facility variation during process	Uncertainty of dosimeter response measurement	Uncertainty of dose determination from calibration function	Uncertainty of measured routine dose (process) used to find accept limits
2.6	3.2	1	0.2	4.2

Include calibration uncertainty when selecting uncertainty for acceptance limits.
Thereby the chosen limits are expected to be valid also for repeated calibrations of the routine dosimeter system

Total uncertainty of dose to product used to find Target dose
s(total) 5.2

The total uncertainty of dose to product is the combined uncertainty of minimum dose and routine dose.
The uncertainty of the transfer dosimeter used for calibration of both dosimeter systems is only counted once.

Required routine dose is calculated as

$D_R(req) =$
$D_R(meas) * (D_t / D_{min}(meas))$

Limits for acceptable variation of routine dose are based on uncertainty for routine dose during process.

Warning limits: 2.5 s.d.
Action limits: 3.5 s.d.

Target dose D_t is calculated as

$D_t = D_{ste}/(1 - k*s(total)/100)$

D_{ste} = Sterilization dose
k = number of standard deviations that minimum dose must be greater than sterilization dose

k =	2
D_t (kGy)	27.9

Traceability chain
Transfer dosimeter
In-plant calibration
Calibrated routine dosimeter
Calibrated dose map dosimeter
Measured routine dose during dose map
Measured minimum dose during dose map
Establish irradiation conditions for sterilization of product
Determine required routine dose $D_R(req)$
Determine target dose D_{ste}
Determine accept limits for routine dose

Arne Miller armi@risoe.dtu.dk
Jakob Helt-Hansen jahh@risoe.dtu.dk
Risø High Dose Reference Laboratory
Risø DTU - Technical University of Denmark
DK-4000 Roskilde, Denmark